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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/863,606	05/23/2001	Julianna Lisziewicz	RGT 7028	2145

7590 07/30/2003

The Law Offices of Valerie E. Looper
77126 Lightfall Court
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EXAMINER
WILSON, MICHAEL C

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 07/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/863,606	LISZIEWICZ ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) *15,16 and 21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 17-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *11* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet* .

Continuation of Attachment(s) 6). Other:
1) CRF Problem Report
2) Notice to Comply.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group II in Paper No. 10 is acknowledged. Applicants elected the species of ddI as the reverse transcriptase inhibitor and Indinavir as the protease inhibitor. The traversal is on the ground(s) that the use of drug in humans is unrelated to the question of patentability, either of the drug, its method of use or its use in combination with another treatment such as a vaccine. This is not found persuasive because the restriction is based on combinations of antiretroviral drugs that have different functions and the burden required to search all combinations of drugs encompassed by the claims.

The requirement is still deemed proper and is therefore made FINAL.

Claims 15, 16 and 21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Claims 1-14 and 17-20 are under consideration as they relate to administering antiretroviral drug therapy comprising ddI and Indinavir until viral replication is effectively suppressed, and then administering a gene delivery complex as claimed.

The information disclosure statement filed 5-12-03 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. The two discs having the references in .pdf is on

file in the Biotechnology Systems Branch and is unavailable to the examiner. The information referred to therein has not been considered. Do not submit IDS references on the same disc as the Sequence Listing. A hard copy of the references is preferred.

The information disclosure statement filed 5-12-03, paper number 11, fails to comply with 37 CFR 1.97(c) because it lacks the fee set forth in 37 CFR 1.17(p). It has been placed in the application file, but the information referred to therein has not been considered.

Specification

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. **The computer readable form (CRF) was not readable. See attached CRF Problem Report**. Applicants must file a "Sequence Listing" accompanied by directions to enter the listing into the specification as an amendment. Applicant also must provide statements regarding sameness and new matter with regards to the CRF and the "Sequence Listing." Applicant is requested to return a copy of the attached Notice to Comply with the reply. Failure to fully comply with the sequence rules in response to the instant office action will be considered non-responsive.

The abstract is objected to because it is not descriptive of the invention.

The first line of the specification needs updated to reflect the fact that 09/153,198 is now US Patent 6,420,176.

The status of US Patent Applications on pg 4, line 28, pg 11, line 23, pg 16, line 29, and pg 21, lines 5, 7 and 8, need updated.

The description of the drawings is objected to because the heading for Fig. 8 on pg 7, line 7, should be Fig. 8A-8C. The heading for Fig. 11 on pg 7, line 26, should be Fig. 11A-11B. The heading for Fig. 12 on pg 8, line 1, should be Fig. 12A-12B. The heading for Fig. 13 on pg 8, line 4, should be Fig. 13A-13C.

Claim Rejections - 35 USC § 112

Claims 1-14 and 17-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Administering an antiretroviral drug therapy comprising ddI and Indinavir until viral replication is effectively suppressed is considered enabled because Finzi taught administering a reverse transcriptase inhibitor and a protease inhibitor suppressed viral replication (Finzi et al. Science. Nov. 14, 1997, Vol. 278, pg 1295-1300). Claims 1-14 and 17-20 are not enabled because the structure of the gene delivery complex that is a "therapeutic genetic immunization" claimed has not been adequately taught in the specification.

The state of the art at the time of filing was that the combination of vector, promoter, route of administration, level of expression and target tissue required to obtain a therapeutic or prophylactic effect using gene therapy was unpredictable. Miller of record (1995, FASEB J., Vol. 9, pages 190-199) review the types of vectors available for *in vivo* gene therapy, and conclude that "for the long-term success as well as the widespread applicability of human gene therapy, there will have to be advances...targeting strategies outlined in this review, which are currently only at the experimental level, will have to be translated into components of safe and highly efficient delivery systems" (page 198, column 1). Deonarain of record (1998, Expert Opin. Ther. Pat., Vol. 8, pages 53-69) indicate that one of the biggest problems hampering successful gene therapy is the "ability to target a gene to a significant population of cells and express it at adequate levels for a long enough period of time" (page 53, first paragraph). Deonarain reviews new techniques under experimentation in the art that show promise but states that such techniques are even less efficient than viral gene delivery (see page 65, first paragraph under Conclusion section). Verma of record (Sept. 1997, Nature, Vol. 389, pages 239-242) reviews vectors known in the art for use in gene therapy and discusses problems associated with each type of vector. The teachings of Verma indicate a resolution to vector targeting has not been achieved in the art (see entire article). Verma also teaches appropriate regulatory elements may improve expression, but it is unpredictable what tissues such regulatory elements target (page 240, sentence bridging columns 2 and 3). Crystal of record (1995, Science, Vol. 270, page 404-410) also reviews various vectors known in the art and indicates that

"among the design hurdles for all vectors are the need to increase the efficiency of gene transfer, to increase target specificity and to enable the transferred gene to be regulated" (page 409).

The state of the art regarding treating retroviral infection was unpredictable. Stricker of record (Medical Hypotheses, June 1997, Vol. 48, pages 527-9) teaches that attempts to develop a vaccine against HIV have been unsuccessful because HIV vaccines do not neutralize HIV (pg 527, last paragraph through all of pg 528). Overall, a lack of understanding about protective immunity to HIV in humans, the sequence variability of HIV and the rapid replication of HIV contribute the ineffectiveness of vaccines against HIV (Bangham of record, Nov. 29, 1997, Lancet, Vol. 350, pages 1617-1621; page 1617, top of col. 1).

The specification teaches a complex comprising i) manosylated PEI and ii) DNA encoding an immunogenic HIV protein operably linked to a promoter. Administration of the complex to a host after drug therapy was followed by an increase in CD4 cells then a decrease in CD4 cells (pg 53).

The specification does not provide adequate guidance for one of skill to use a gene delivery complex comprising "foreign genetic material" as a "therapeutic genetic immunization" as claimed. The results described in the specification are not considered therapeutic because the overall result does not result in a net increase in CD4 cells. In addition, it cannot be concluded that the gene complex caused the initial increase in CD4 cells because the experiment did not include controls - animals that did not receive drug therapy or the gene complex. The specification does not provide adequate

guidance indicating the increase in CD4 was caused by the gene complex - the drug therapy could have caused the increase in CD4. The specification did not teach treating animals that were already infected or challenging the animals after they were given DermaVir. For administration of foreign genetic material to be a "therapeutic genetic immunization", the specification must overcome the unpredictability in the art by adequately describing the structure of the "foreign genetic material" used, the dosage and route of administration that results in a therapeutic effect or "immunization." Without such guidance it would require one of skill in the art undue experimentation to overcome the unpredictability in the art regarding gene therapy and retroviral therapy to determine the combination of elements required to obtain a therapeutic or prophylactic effect against retroviral infection using "foreign genetic material. Therefore, the specification does not enable "therapeutic genetic immunization" using a gene delivery complex comprising "foreign genetic material" as claimed.

Claims 1-14 and 17-20 are not enabled because the specification does not provide adequate guidance to determine any complex that has a "specific affinity for a receptor of an antigen presenting cell" as claimed.

The specification does not define "affinity" and does not teach any sugar, PEI, PEI derivative or mixture thereof that has a "specific affinity for a receptor on an antigen presenting cell". The art at the time of filing did not teach sugars, PEI, PEI derivatives or mixtures thereof that had a "specific affinity for a receptor on an antigen presenting cell." For example, the specification contemplates using the mannose receptor for entry into dendritic cells; however, the mannose receptor is also found on macrophages

(Stahl, Feb. 1998, Curr. Opin. Immunol., Vol. 10, pages 50-55; page 51, col. 2). The specification also contemplates using mannosylated-PEI which binds to the mannose receptor; however, the PEI component of mannosylated-PEI may be internalized via the asialoglycoprotein receptor which is found on non-APCs (e.g. hepatocytes) (page 16, last sentence). The specification does not teach that mannosylated-PEI is specific to the mannose receptor on APCs and that the PEI component could not be used to bind the asialoglycoprotein receptor on a non-APC (e.g. hepatocyte). It would have required one of skill in the art undue experimentation to determine agents that specifically bound to receptors on antigen presenting cells and not to other receptors. Therefore, agents having a "specific affinity" for receptors on antigen presenting cells are not enabled.

The specification does not enable suppressing any viral replication using "antiretroviral drug therapy" (claim 1) other than retroviral replication. The specification and the art do not teach suppressing replication of any virus using antiretroviral drug therapy other than retroviral replication. In fact, many of the antiretroviral drug therapies describe in the specification inhibit reverse transcriptase, which is specific to retroviruses. In particular, the combination of inhibiting reverse transcriptase and protease is specific to retroviruses. It would require one of skill undue experimentation to determine how to suppress replication of any virus using antiretroviral drug therapy other than retroviruses.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 and 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the antiretroviral drug therapy and gene delivery complex are not administered to a host that is infected with a retrovirus. The claim should clearly set forth that the drug therapy and gene delivery complex are administered to something.

Claim 1 is indefinite because antiretroviral drug therapy does not suppress and "viral replication" as claimed. To be commensurate in scope, the antiretroviral drug therapy should suppress retroviral replication.

The term "effectively" in claim 1 is indefinite. The term is relative and does not have a definition in the art or the specification. As such the metes and bounds of when replication is "effectively" suppressed cannot be determined.

The term "foreign" in claim 1-6 does not make sense. The term is relative. The claim does not clearly set forth to what the genetic material is foreign. Especially in view of the fact that the genetic material is not administered to a host of any kind.

It cannot be determined how "foreign genetic material" relates to the "non-viral vector" (claim 1). It cannot be determined if the two components are mutually exclusive or if the components share overlap. If the components share overlap, it cannot be determined how the components overlap.

The term "specific affinity" is indefinite (claim 1, 11). It cannot be determined if "specific" in context means the complex only has affinity for a receptor on an antigen-

presenting cell or if the complex has a preference for a receptor on an antigen-presenting cell. Therefore, the metes and bounds of the complex cannot be determined.

The metes and bounds of "gene delivery complex" that have an affinity for a receptor on an antigen-presenting cell cannot be determined (claim 1). It is unclear if the complex must bind to a receptor or if the complex merely has a chemical attraction to the receptor.

The metes and bounds of "reverse-transcriptase dependent virus" in claim 3 is indefinite. It cannot be determined if the virus must have reverse transcriptase to exist, if the virus must have reverse transcriptase to replicate, or if the virus must have reverse transcriptase to infect cells. The metes and bounds of what applicants consider "dependent" cannot be determined.

The metes and bounds of what applicants consider a "substantial portion" of a replication defective HIV (claim 4-6) cannot be determined. How substantial is a "substantial portion?"

The metes and bounds of what applicants consider "an integrase negative mutant of a dual-tropic primary isolate of a human immunodeficiency virus" cannot be determined (claim 6). It is unclear if the virus does not encode an integrase or if the virus is merely deficient at producing functional integrase. It is unclear how a virus is "dual-tropic" because the term does not have a definition in the art or the specification. The metes and bounds of a primary isolate of HIV are unclear because it cannot be determined if the term "primary" is limited to a virus isolated directly from a patient or

whether the term encompasses a virus isolated directly from a patient and maintained over a period of time.

The phrase "the reading frames of the integrase gene" in claim 7 lacks antecedent basis in claim 6. The phrase also does not make sense because claim 6 requires the virus is "integrase negative." An "integrase negative" virus does not have reading frames of an integrase gene.

Claim 8 is unclear. The foreign genetic material or the non-viral vector may be DNA, but the complex is not DNA. It is unclear if the complex of claim 1 further comprises "one or more agents... ...sugars, polyethylenimine..." or if the "one or more agents" is limiting one of the terms in claim 1.

The phrase "complex is DNA and one or more agents" (claim 8) is grammatically incorrect. Use of one (singular) and agents (plural) in combination is improper. Upon correcting the error, the species in the Markush group may also require correcting.

Claim 8 is indefinite because the Markush Group is improper. Sugars, PEI, and PEI derivatives are not species that share a genus. The structure of sugars is materially distinct and separate than that of PEI or PEI derivatives. As such, the group is improper.

Claim 9 is indefinite because "sugar-modified polyethylenimine" does not clearly set forth the structure of the agent. It is unclear how the PEI is modified with sugar - it the sugar attached or merely used to alter the structure of PEI without attaching. It is unclear whether the "sugar-modified polyethylenimine" further limits the PEI or the PEI derivative in claim 8.

Claim 10 is indefinite because it is unclear if glucose is further limiting the "sugars" or the "derivatives" of PEI in claim 8.

The phrase "antiretroviral drug combination" in claim 17 lacks antecedent basis.

The metes and bounds of what applicants consider "highly active" antiretroviral drug therapy cannot be determined (claim 17). It is unclear if the phrase refers to a particular combination of drugs or any drug or drug combination that has a particular activity. If the phrase refers to drug or drugs that have a particular activity, the level of activity for a treatment to be considered "active" cannot be determined. While the phrase was known in the art, the phrase does not have a definition in the art or the specification. Therefore, the metes and bounds of such therapies cannot be determined.

To be in proper Markush format, claims 18 and 20 should have the phrase "selected from the group consisting of".

Claims 19 and 20 contain the trademark/trade name delavirdine, abacavir, adefovir, nevirapine, efavirenz, lubocavir, PMPA, PMEA, indinavir, saquinavir, ritonavir, nelfinavir, and GW41. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the

goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe reverse transcriptase inhibitors and protease inhibitors and, accordingly, the identification/description is indefinite.

In claim 19, a comma is required between PMPA and PMEA.

Claims 1-14 and 17-20 are free of the prior art because the prior art did not teach or suggest administering ddI and Indinavir until viral replication is effectively suppressed, and then administering a gene delivery complex as claimed. Finzi et al. (Science. Nov. 14, 1997, Vol. 278, pg 1295-1300) taught administering reverse transcriptase inhibitors and protease inhibitors to HIV patients. However, Finzi et al. did not relate to administering DNA encoding the marker protein luciferase to the brain of mice as taught by Boussif et al (PNAS, Aug. 1995, Vol. 92. pg 7292-7301) of record, administering DNA encoding a marker protein to cells *in vitro* as taught by Zanta et al. (Bioconjugate Chem. 1997. Vol. 8. pg 839-844) of record, administering DNA encoding a marker protein to cells *in vitro* as taught by Behr et al. (US Patent 6,013,240) of record, or administering virus encoding integrase-defective HIV to cells *in vitro* as taught by Cara et al. (Virology, 1995, Vol. 208, pg 242-248).

The following references have also been reviewed:

Lori, Science, 1994, Vol. 266, pg 801-805;

Lori, AIDS Res. Hum. Retrovir., 1997. Vol. 13, pg 1403-1409;

Lori, AIDS Res. Hum. Retrovir., 1995, Vol. 11, pg 1149-1151;

Hollinshead, US Patent 5,747,526;

Malley US Patent 5,521,161;

Malley, US Patent 5,736,526;

Lin, US Patent 5,719,132;

Lori, US Patent 6,046,175 ;

Malley, US Patent 6,093,702 ;

Lori, US Patent 6,194,390 ;

Critchfield, US Patent 6,274,611;

Lisziewicz, US Patent 6,114,312;

Lisziewicz, US Patent 6,251,874;

Lisziewicz, US Patent 5,977,086.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 and 17-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,420,176 in view of the disclosure of 6,420,176. The claims of '176 are directed toward a gene delivery complex comprising DNA encoding an immunogenic protein operably linked to a promoter and monosylated polyethylenimine. The claims of '176 do not require administration as required in the instant claims or administration of antiretroviral drug therapy. MPEP 804 states the specification may be used as a dictionary to learn the meaning of a term in the patent claim. In this case, one of skill would look to the specification to determine the asserted utility of the product. The disclosure taught administering the gene delivery complex after suppressing viral replication using antiretroviral drug therapy (col. 12, lines 11-51, see especially lines 20-27). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the gene delivery complex in combination with drug therapy as claimed.

Claims 1-14 and 17-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,130,089 in view of the disclosure of 6,130,089. '089 claims a method of

administering a gene delivery complex but does not claim the method requires administering an antiretroviral drug therapy. However the disclosure of '089 taught using the method after administering an antiretroviral drug therapy and suppressing retroviral replication (col. 7, lines 5-33).

Claims 1-14 and 17-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 10/081922. Although the conflicting claims are not identical, they are not patentably distinct from each other because they overlap in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-0120.

Questions of formal matters can be directed to the patent analyst, Dianiece Jacobs, who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at (703) 305-3388.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached on (703) 305-4051.

The official fax number for this Group is (703) 308-4242.

Michael C. Wilson

MICHAEL WILSON
PRIMARY EXAMINER